DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

93655d

FOOD & DRUG ADMINISTRATION
466 FERNANDEZ JUNCOS AVENUE
SAN JUAN, P.R. 00901-3223

October 25, 2002

WARNING LETTER
SJN-03-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Edward Ludwig,
Chairman Executive Officer/President
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1880

Dear Mr. Ludwig:

During an inspection of your establishment, Becton Dickinson Caribe LTD, located at Road 31, Km 24.3, Juncos PR 00777, on June 3, through June 28, 2002, our investigator determined that your firm manufactures: anesthesia, regional block radiology, biopsy needles (Class II); suprapubic drainage catheters, drainage valves (Class II); and caps and adapters (Class I). All of these are medical devices, as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated with the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820), as follows.

1. Your firm failed to validate the manufacturing process for the Whitacre needles, molded with [redacted] with a high degree of assurance that it is approved according to established procedures, as required by 21 CFR 820.75(a). For example, your validation records fail to demonstrate that all the requirements described in the protocol were executed as required. There are also no records demonstrating that the equipment was operated for [redacted] minutes to show the equipment is capable of producing good quality product. There are no records to demonstrate that all the operating parameters (e.g. maximum, minimum and nominal parameters) were verified and that all the sample were collected and tested in accordance to the validation protocol (e.g. possible defects and leaks). (FD-483, item #1)

2. Your firm failed to analyzed, identify and document existing and potential causes of non-conforming product and other quality problems, as required by 21 CFR 820.100(a)(1). For example, not all sources of the quality data (e.g. non-conformance material reports, internal audits, complaints, in-process and finished device testing) are utilized to identify potential or existing causes of the non-conforming products and other quality problems. There is no procedure for the statistical and non-statistical analysis of the product and quality problems. (FD-483, item #2)

3. Your firm failed to ensure that the information related to quality problems or non-conforming product is disseminated to those directly responsible for assuring the quality of such product, as required by 21 CFR 820.100(a)(6). For example, incorrect information regarding the amount of spinal needle defects found during periods of year 2001 was reported. Data related to the different types and amounts of defects described in the consumer complaints was not submitted to management for evaluation. Also, non-conformance reports were not submitted for review by management. (FD-483, item #3)

4. Your firm failed to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a). For example, corrective and preventive action Procedure QC 06-014 was not implemented as required. Although a CAPA report was prepared as a result of several complaints related to holes observed at the hub area of Whitacre Needles 25 x 3 ½, there is no documentation to demonstrate that potential corrective and preventive actions were discussed and evaluated. There is no data to show that an investigation assigned on 5/01 was conducted and that corrective actions to prevent recurrence were taken prior to the planned completion date of January 2002. (FD-483, item #4)

5. Your firm failed to identify actions needed to correct and prevent recurrence of non-conforming product and other quality problems, as required by 21 CFR 820.100(a)(3). For example, although your firm is aware that "big flares" occur during the insert molding process of the needles causing the holes in the hub defect, you have not identified any corrective and preventive actions to prevent this problem. (FD-483, item #5)

6. Your firm failed to follow procedures for products that do not conform to specified requirements, as required by 21 CFR 820.90(a), 21 CFR 820.181, and 21 CFR 820.184. For example, non-conformance reports are not always being completed as required when non-conforming conditions of materials, components or process are detected. (FD-483, item #7)

7. Your firm fails to have sufficient personnel with the necessary training to assure that all activities required by 21 CFR Part 820 are correctly performed, as required by 21 CFR 820.25. For example not all of the employees approving the validation protocols and reports for the Whitacre needles molded with [redacted] have been trained in process validation. (FD-483, item #8)

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations have been corrected. You also must promptly initiate permanent corrective and preventive action on your quality system. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

We have received your letter dated July 15, 2002, which replied to the FDA 483 issued on June 28, 2002. The corrective actions that you plan appear to be adequate and will be verified during the next follow-up inspection. However, please indicate in your response if you intend to continue releasing product to the market prior to completing the revalidation exercise.

Please update this office in writing within 15 working days of receipt of this letter of the status of the actions taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Carmelo Rosa, Compliance Officer at the address on the letterhead.

Evelyn Bonnin
Acting District Director